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## (54) APPARATUS FOR MONITORING HEART-BEAT ACTIVITY

(71) We, F. HOFFMANN-LA ROCHE & Co. AKTIENGESELLSCHAFT, a Swiss Company, of 124-184 Grenzacherstrasse, Basle, Switzerland, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to an apparatus for monitoring heart-beat activity by means of electrical signals derived from ultrasonic Doppler shift information.

The invention relates generally to electrical signal processing techniques utilized with an ultrasonic exploratory system and, more particularly, to signal analyzing in fetal monitoring.

In ultrasonic exploratory scanning, physiological data is derived from a patient, for monitoring and/or therapeutic purposes, by transmitting ultrasonic energy into the patient's body and then collecting and processing the data derived for diagnostic purposes. However, problems are often incurred in analyzing such data due to the signals derived from the multiple Doppler shifted reflected waves and associated noise collected from the body site being investigated.

In particular, in the field of fetal monitoring, the frequent movement of the fetus adds to the problem of deriving reliable signals indicative of fetal heart-beat rate. The problem is intensified even more as a consequence of the multiple Doppler shifted reflected waves generated by the front and rear wall of the heart, heart valves, etc., in addition to the nonsynchronous impulse noise caused by the fetal and mother movements.

Naturally, processing of multiple Doppler signals with background noise within a single heart-beat, if processed as consecutive heart-beat signals, would produce a false indication of the fetal heart-beat rate, and therefore provide unreliable instrumentation. The diagnosis resulting from such indications may even cause the omission of emergency procedures in some cases, and the commission of unwarranted emergency procedures in others. The use of long term averaging techniques is not permissible since it is important that rapid changes in fetal heart-beat rate be observed.

One improvement made to help obviate such problems is disclosed in U.S. Patent No. 3,763,851. The latter improvement discloses an ultrasonic apparatus for monitoring heart-beat activity from Doppler shift information derived from heart-beat motion. The Doppler shift information is fed to an adjustable resonant circuit for de-emphasizing Doppler signal frequency content other than that about the resonant circuit frequency, and comparing input signals to, and output signals from the resonant circuit for detecting a phase difference, if any, which is employed for adjusting the frequency of the resonant circuit at a preselected rate. Such a technique provides a phase locked tracking filter which helps to suppress and eliminate undesired signals.

Despite the achievement of displaying reliable fetal heart-beat rates with the technique disclosed in the above-referenced patent specification, it was found that a still more reliable fetal heart-beat rate count could be attained from the Doppler signals to provide an automatic operating system to handle the quick transition from tachycardia to bradycardia conditions, which is highly desirable for monitoring fetal heart-beat rates.

The purpose of the present invention is therefore to provide an apparatus to derive a one-per-beat fetal heart rate signal of improved accuracy by suppression of signals indicative of other motions within the body and nonsynchronous impulse noise.

Accordingly, the invention provides appa-

ratus for monitoring heart-beat activity by means of electrical Doppler signals derived from ultrasonic Doppler shift information comprising: filter means to pass a first band of frequencies of said electrical Doppler signals and selectively actuable to pass a second band of frequencies of said signals in lieu of the first band; retunable resonant circuit means de-emphasizing in the passed band of frequencies, frequency content other than that of the resonant circuit frequency for providing an output signal indicative of heart-beat rate; phase detector means responsive to any phase shift between input signals to and output signals from the resonant circuit means, for returning the resonant circuit means at a preselected rate so as to reduce the phase shift; timing means connected from the input of the resonant circuit means and to the phase detector means, for inhibiting the response of the phase detector means in the time intervals between selected input signals of the resonant circuit means by means of blanking pulses derived from said selected input signals, said timing means being selectively actuable to define a first or a second blanking period; and rate detector means for actuating said filter means and said timing means in response to a signal representative to heart-beat rate going above or below predetermined threshold values.

In a preferred form, the apparatus according to the invention includes first peak detector means for supplying input signals to said timing means; and second peak detector means for deriving said output signals from the resonant circuit means.

Suitably the rate detector means include first switch means toggled in response to said signal representative of heartbeat rate crossing a first preselected threshold value for actuating said filter means to pass said second band of frequencies, and second switch means toggled in response to said signal representative of heart beat rate crossing a second preselected threshold value for actuating said timing means to define said second blanking period for inhibiting the response of said phase detector means.

In order that the invention may be readily understood, a preferred embodiment thereof will now be described in more detail, by way of example, with reference to the accompanying drawing, in which:

Figure 1 is a voltage (U) versus time (t) waveform diagram to show components of Doppler detected fetal heart motion in relation to EKG fast (curves a and b) and slow (curves c and d) cardiac activity; and

Figure 2 is a block diagram of an apparatus for processing heart-beat rate signals according to the present invention.

As a consequence of extensive clinical investigation of simultaneous Doppler and fetal scalp EKG recordings, the meaning and behaviour of the detail in the Doppler signal have resulted from an analysis which has revealed distinctions in the Doppler signal make-up at different frequency ranges. At a fetal heart-beat rate over about 140 beats per minute (curves a and b in Fig. 1), it was found that there are typically two Doppler components, one clearly related to the P-wave, probably representing atrial contraction, and a second occurring immediately after the QRS, probably representing mitral valve closure. By analogy with an electrocardiogram, in Figure 1, these are respectively labeled $D_1$ and $D_2$. Preliminary investigation shows their relation in time is constant at all heart-beat rates. These are substantially large amplitude signals which is not surprising since the mitral and tricuspid valves are the largest and fastest moving objects within the physiological make-up.

At slower heart-beat rates or those below about 130 beats per minute (curves c and d) another Doppler component becomes evident in diastole, specifically that designated as D3. This event is probably related to mitral or tricuspid opening. It would appear that D3 emerges with D4 at higher fetal heart-beat rates, but as the rate slows it appears to move away from D4 toward D2. Doppler component D3 appears not to be constant, but when it occurs it is troublesome to counting circuits.

As will become evident, after extensive evaluation and testing, the applicant has devised an improved detection circuit for deriving an improved beat-to-beat fetal heart-beat rate signal by diminishing the effect of Doppler components D3 and D4 as well as other undesired noise by automatic switching circuitry which responds to preselected heart-beat rate values to effect changes in bandpass filtering and tuning of blanking circuitry to implement operation of a resonant circuit to act as a tracking filter following the basic harmonic, D2, of the Doppler signals.

In Figure 2, a derived raw ultrasonic Doppler signal is fed via lead 31 to an amplifier 11 and thence through an AGC (automatic gain control) feedback unit 12 which together with amplifier 11 serves to rectify integrate and normalize the incoming signal to form a smooth envelope of the signal. The processed signal is fed to each of a pair of bandpass filters 13 and 14 having respectively upper limit frequencies corresponding to heart-beat rates of around 120 and 150 beats per minute, at a roll-off of 24 db/octave and each having a lower limit frequency corresponding to a heart-beat rate of around 30 beats per minute at a rolloff of 18 db/octave.

A switching unit 15 comprising, for ex-

ample, a field effect transistor pair, selectively connects one of the filters 13, 14 to each of an adjustable resonant circuit 17 and a peak detector 18. The switching operation is controlled by a conventional rate detector 16 which is connected via lead 32 from a heart-beat rate counter. In the present embodiment the rate detector 16 is designed to respond to rates of the heart-beat rate counter above a preselected value, e.g. 100 beats per minute, to operate switch 15 for passing signals emitted from filter 14, whereas the rate detector responds at rates below the preselected value to operate switch 15 for passing signals emitted from filter 13.

As disclosed in the above referenced patent specification, the resonant circuit 17, which acts as a narrow band filter locking on to the fundamental frequency of the input, comprises a resistance R, a capacitance C and a variable inductance L (these circuit elements are not shown in Fig. 2). In the present embodiment, the resonant circuit is, for example, electronically tuned from 0,5 to 4 Hz, which corresponds to a heart-beat rate range from 30 to 240 beats per minute.

Positive peaks of the passed signal trigger the peak detector 18 which in turn triggers a one shot unit 19. One shot unit 19 is designed to generate output pulses having one of two refractory periods, as determined by switch 21. The duration of an output pulse of one shot unit 19 is called a refractory period because one shot unit 19 once energized cannot be re-triggered over a period coinciding with the length of the output pulse. Switch 21 is responsive to the output of rate detector 16, which responds to a preselected value of the output of the heart-beat rate counter to effect a change of the refractory period of the output pulse generdated by one shot 19. In the present embodiment, a one shot refractory period of 100 ms is generated when the fetal heart-beat rate is above 140 beats per minute and a one shot refractory period of 350 ms is generated when the fetal heart-beat rate is below 140 beats per minute. It is noted that switch 21 responds to a higher value on the heart-beat rate counter than that responded to by switch 15.

The input of the resonant circuit A is connected to the peak detector 18 and the ouput of resonant circuit 17 is connected to a peak detector 22. A phase detector 23 compares the outputs of the two peak detectors 18 and 22 to provide an output signal representative of any phase shift between them. The output signal of phase detector 23 is integrated by an integrator 24 for retuning the resonant circuit 17 by way of its inductance L. The output of peak detector 22 is also fed to the heart-beat rate counter via lead 34 and other selected circuitry such as, for example, a credence checking circuit.

The operation of the detection circuit is as follows. Assuming the fetal heart-beat rate of a fetus being monitored is above 100 beats per minute, switch 15 would have been acted on by rate detector 16 to connect the output of bandpass filter 14 to the input of resonant circuit 17 to increase the bandpass monitoring range, for the reason that as the fetal heart-beat rate increases above 100 beats per minute less noise is present in the Doppler derived signal. The resonant circuit 17 to which the signals are passed acts as a narrow band filter locking on to the fundamental frequency or basic harmonic of the Doppler signals to de-emphasize noise and associated higher harmonic signals occurring at the higher end of the resonant circuit bandpass characteristic.

The resonant circuit 17 thus responds strongly to its input signal in terms of voltage amplitude at one desired frequency and discriminates against other frequencies, whereby the desired or tuned frequency is that which the resonant circuit is adjusted to, over for example, three to ten seconds (the slew rate of the resonant circuit) which is the time it might take for the resonant circuit to be retuned from .5 to 4 Hz. Should the resonant circuit be tuned to the precise frequency of the input signal, the phase shift through the circuit as sensed at phase detector 23 will be zero. If the frequency of the tuned resonant circuit is either above or below the incoming frequency, the phase shift sensed by the phase detector 23 is used as an error correcting signal via integrator 24 to retune the resonant circuit 17 to be precisely in tune with the incoming signal.

The output of the integrator acts as the control voltage which determines the slew rate of the resonant circuit. The slew rate is made to be longer than the lowest period of the resonant circuit, which in the present embodiment is, for example, two seconds or one half cycle per second. Clearly the slew rate should not exceed a value that would not closely follow or track the actual incoming cardiac activity to which the filter is responding. The resonant circuit is then, in effect, forced to track (as modified by the slew rate) the incoming signal, whereby it will not respond to impulse artifact of even 2, 3 or 4 motions per fetal cardiac cycle unless these motions are precisely harmonically related. The operation of the resonant circuit was found to be enhanced by utilizing peak detectors 22 and 18 providing the trigger signals to be supplied to phase detector 23 for the reason that peak detection allows for better signal detection in the presence of noise and eliminates base line wandering problems.

Upon the change of the state of the output of the peak detector 18 by detection of the peak input signal, one shot unit 19 is triggered. The one shot unit provides a refractory period which serves as a blanking pulse to inhibit operation of the phase detector in response to unwanted noise within that period which might include attenuated portions of signals D3 and D4 (illustrated in Figure 1). Accordingly, the window blanking prevents retuning of the resonant circuit 17 by such signals. For optimum operation, the blanking period is varied to be of a shorter duration at higher heart-beat frequencies and of a longer duration at lower heart-beat frequencies, for example, as discussed with regard to Figure 1. Further, at a higher heart-beat rate a shorter blanking period suffices to override D4 whereas at a lower heart-beat rate a longer period is necessary to override D3 and D4.

To enable the resonant circuit to respond properly to an increase or decrease in the derived Doppler fundamental frequency, switching of the blanking window refractory periods and filters 13 and 14, should not occur simultaneously. The best results are obtained when, assuming a 100 beats per minute as criteria for the filter switching, the switching of the one shot refractory period occurs at a heart-beat rate meter reading of roughly 140 beats per minute as detected by rate detector 16.

As may be seen, the switching of the filters and the blanking window refractory periods, provide a concerted action whereby the filters and resonant circuit combine to deter a quick jump from the previously recorded heart-beat rate and whereby the blanking window refractory periods serve to improve the reliability of reading low heart-beat rates. This, in essence, enables the sysem to handle both tachycardia and bradycardia events with optimum reliability.

It should be understood, of course, that although only two bandpass filters and two one shot refractory periods are disclosed, three or more of each might be employed, the number of bandpass ranges and the number of refractory periods not being necessarily the same, e.g. three bandpass ranges to cover a heart-beat rate range from about 30 to 240 beats per minute and 4 one shot refractory periods.

WHAT WE CLAIM IS:—

1. Apparatus for monitoring heart-beat activity by means of electrical Doppler signals derived from ultrasonic Doppler shift information comprising: filter means to pass a first band of frequencies of said electrical Doppler signals and selectively actuable to pass a second band of frequencies of said signals in lieu of the first band, retunable resonant circuit means de-emphasizing in the passed band of frequencies, frequency content other than that of the resonant circuit frequency for providing an output signal indicative of heart-beat rate; phase detector means responsive to any phase shift between input signals to and output signals from the resonant circuit means, for retuning the resonant circuit means at a preselected rate so as to reduce the phase shift; timing means connected from the input of the resonant circuit means and to the phase detector means, for inhibiting the response of the phase detector means in the time intervals between selected input signals of the resonant circuit means by means of blanking pulses derived from said selected input signals, said timing means being selectively actuable to define a first or a second blanking period; and rate detector means for actuating said filter means and said timing means in response to a signal representative of heart-beat rate going above or below predetermined threshold values.

2. Apparatus according to claim 1 including: first peak detector means for supplying input signals to said timing means; and second peak detector means for deriving said output signals from the resonant circuit means.

3. Apparatus according to claim 1 wherein said rate detector means include: first switch means toggled in response to said signal representative of heart-beat rate going above or below a first preselected threshold value for actuating said filter means to pass said second band of frequencies, and second switch means toggled in response to said signal representative of heart-beat rate going above or below a second preselected threshold value for actuating said timing means to define said second blanking period for inhibiting the response of said phase detector means.

4. Apparatus according to claim 3 wherein said first preselected threshold value is smaller in terms of beats per minute than said second preselected threshold value.

5. Apparatus for monitoring heart-beat activity substantially as hereinbefore described with reference to, and as illustrated in, Figure 2 of the accompanying drawings.

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*This drawing is a reproduction of the Original on a reduced scale*

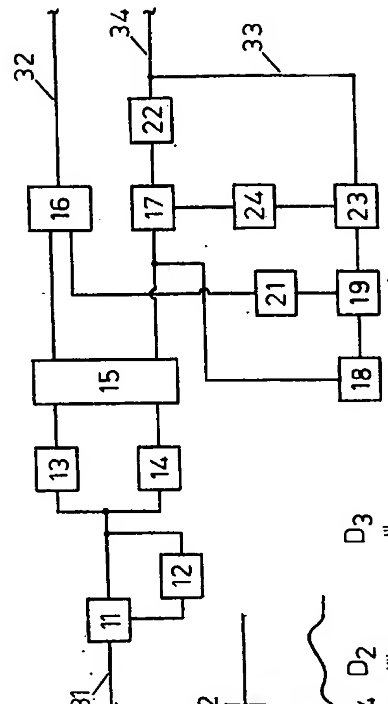

Fig.2

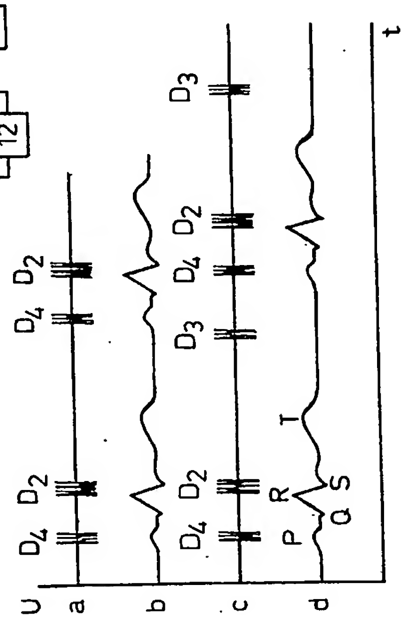

Fig.1